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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,927	09/15/2000	Marvin J. Slepian	MJS 101	3540

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EXAMINER	
KREMER, MATTHEW J	
ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/662,927	SLEPIAN, MARVIN J.
	Examiner	Art Unit
	Matthew J Kremer	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,19,22,23,27,28 and 30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,19,22,23,27,28 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. In view of the Appeal Brief filed on 3/25/2003, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below for claims 27 and 28.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-9, 19, 22, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,146,029 to Ellinwood, Jr. Ellinwood, Jr. discloses an implantable device which includes a sensor and a housing which stores and evaluates data and dispenses medication. The medication dispenser causes the device to undergo a configurational change in the device by movement of its parts while dispensing. The sensors can detect pH changes, ionic changes, glucose, and electrical changes. In regard to claims 4-5 and 22, telemetry means is employed to transmit information to various peripheral devices.

4. Claims 1-9, 19, 22-23 and 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,248,080 to Miesel et al. Miesel et al. teaches an implantable medical device which telemeters stored data or real-time-sensed data to an external device to derive intracranial gage pressure. (Abstract of Miesel et al.). The medical device includes a temperature or pressure sensor implanted into the brain. The implantable device includes a means of receiving, storing, and transmitting the signals to an external device. The system includes the implantable medical device (IMD) delivering an antibiotic, an antiviral agent, an anti-inflammatory agent, a vaccine, or a drug. (column 6, lines 27-42 of Miesel et al.). In regard to claim 1, Miesel et al. discloses that the delivery of therapy can include actions such as shunt opening or closing or a valve opening or closing. (column 13, line 56 to column 14, line 6 of Miesel et al.). The device is considered to undergo a configurational change when the delivery or cessation of delivery of a therapy occurs since such an action accompanies physical

movement of parts. In regard to claims 2-3, the IMD includes RAM. (column 9, lines 1-20 of Miesel et al.). In regard to claims 4-5, telemetry can be employed. (column 8, lines 43-53 of Miesel et al.). In regard to claim 9, temperature, pH, or oxygen saturation can be calculated. (column 9, lines 45-52 of Miesel et al.). In regard to claim 23 and 31-32, the system can include transmission of alarms and information via telephone, hardwire, cell phone, satellite, or internet. (column 17,lines 57-65 of Miesel et al.).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,146,029 to Ellinwood, Jr. as applied to claim 1 in view of U.S. Patent 5,411,551 to Winston et al., and further in view of U.S. Patent 6,092,530 to Weissman et al. Ellinwood, Jr. does not teach the use of a sensor on a stent. Ellinwood, Jr. teaches that glucose level sensors can be used. (column 7, lines 1-15 of Ellinwood, Jr.). Ellinwood, Jr. does not teach a particular form of glucose sensor. Winston et al. teaches a stent for the sensing of glucose. (Abstract of Winston et al.). The glucose sensor of Winston et al. is the type of sensor that Ellinwood, Jr. suggests that can be

used in the implanted device. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Ellinwood, Jr. to include the sensor of Winston et al. for determining blood glucose since Ellinwood, Jr. requires a glucose sensor and Winston, Jr. teaches one such sensor. The combination does not teach a sensor which measures the fouling of the device. Weissmann teaches a sensor on a stent that is used to monitor fouling of the stent. (Abstract of Weissman et al.). Weissmann teaches that it is desirable to be able to monitor such conditions in order to evaluate the health of the patient. (column 1, lines 28-33 of Weissmann). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include the fouling sensor of Weissman since it is desirable to be able to monitor such conditions in order to evaluate the health of the patient. In regard to claim 28, the sensor of Weissmann measures the build-up in an artery such as restenosis, toxin, viral/DNA/bacterial entities, wear particles, and cancer cells.

Response to Arguments

7. In regard to claims 1-9, 19, 22, 23, and 30-33, Applicant's arguments filed in the Appeals Brief filed on 3/25/2003 have been fully considered but they are not persuasive and the rejections are maintained. In regard to the Ellinwood, Jr. et al reference, Applicant alleges that (1) there is no specific support for a means of sensing in Ellinwood, Jr, (2) Ellinwood, Jr. does not teach that the sensors are part of the device, (3) the present application is distinguished from Ellinwood, Jr. in that the inclusion of an

actuator in the present system causes a configurational change in the device as a result of input from the sensors, (4) Ellinwood, Jr. does not discloses a system whereby data goes from sensors through an actuator to cause a change in the device. In regard to claim 1, Ellinwood, Jr. teaches an implanted device with a chemical sensor 60 (Fig. 4 of Ellinwood, Jr.) for monitoring glucose level. (column 7, lines 1-5 of Ellinwood, Jr.). The device includes an actuator in the form of a medication dispenser 62, which undergoes a configurational change by dispensing drugs in response to the glucose level. In regard to claim 33, Ellinwood, Jr. teaches an implanted device with a chemical sensor 60 (Fig. 4 of Ellinwood, Jr.) for monitoring glucose level. (column 7, lines 1-5 of Ellinwood, Jr.). The device includes an actuator in the form of a medication dispenser 62, which undergoes a configurational change by dispensing drugs in response to the glucose level. Elliwood, Jr. further teaches the use of an external unit configured to control the device. (Figs. 21-22 of Ellinwood, Jr.). In regard to Applicant's contention that there is no specific support for a means of sensing in Ellinwood, Jr., Ellinwood, Jr. clearly teaches sensors in column 7, lines 1-5. In regard to Applicant's contention that Ellinwood, Jr. does not teach that the sensors are part of the device, Ellinwood, Jr. clearly teaches sensors are part of the invention as stated in column 7, lines 1-5. It may be that the Applicant is arguing that the sensor must be encased in the same housing as the rest of the device but no such language appears in the claims. In regard to Applicant's contention that the present application is distinguished from Ellinwood, Jr. in that the inclusion of an actuator in the present system causes a configurational change in the device as a result of input from the sensors, the Examiner categorizes the

physical change in the dispenser as a configurational change, which is triggered by the sensor readings. In regard to the Applicant's contention that Ellinwood, Jr. does not discloses a system whereby data goes from sensors through an actuator to cause a change in the device, no such language appears in claims 1 and 33 but only recites a device that comprises a sensor and an actuator configured for implementing a response to the monitored data by causing a configurational change. Elliswood, Jr. teaches a device comprising a sensor and a dispensor which undergoes a configurational change to deliver drugs in response to the sensor readings.

In regard to the Miesel reference, the Applicant contends that (1) there is no direct interaction from sensors and the device via an actuator, (2) the device is not responsive to signals generated as a result of communication between the sensors and external manipulation, and (3) the responsive element is for drug delivery. In regard to claims 1 and 33, Miesel teaches an implantable medical device system comprising one or more temperature and/or pressure sensor, a drug dispenser that undergoes a configurational change by opening valves and shunt and the drug dispenser. (column 6, lines 27-42 of Miesel). The drug dispenser is controlled by either the external device or by the implanted device in response to the sensors. (column 6, lines 27-42 of Miesel). In response to the Applicant's contention that there is no direct interaction from sensors and the device via an actuator, there is no such language in claims 1 and 33. In response to the Applicant's contention that the device is not responsive to signals generated as a result of communication between the sensors and external manipulation, the Examiner disagrees since the external device can be used to control

the drug dispenser and causing the implanted device to generate an alarm. (column 6, lines 42-51 of Miesel). It should be noted that the embodiments listed in column 5, line 61 to column 7, line 8 of Miesel can be combined since Miesel teaches that they can. (column 5, lines 61-63 of Miesel). In response to the Applicant's contention that the responsive element is for drug delivery, this argument is irrelevant since the claim language is not excluding drug delivery. In response to the Applicant's contention that Miesel does not teach a data storage means and the data storage means is configured to be placed contiguous with the device (claims 2 and 3), the Examiner disagrees since Figs. 1a-d shows that there is memory in the implanted device. In regard to claims 6 and 7, the device includes nested loops since the device is constantly sensing data, evaluating data, determining if an alarm or drug delivery should take place. Such loops take place between the sensor, the implanted device, the external device, and the drug delivery. In regard to claim 30, Miesel teaches that the sensors can be coupled in a string to the implanted device. (column 8, lines 54-65 of Miesel). In response to the Applicant's contention that Miesel does not teaches the transmission of data from a computer, phone, or computer via internet (claims 23, 31, and 32), the Examiner respectfully disagrees since Miesel teaches that information from the sensors can be transmitted via phone, hardwire, satellite, hospital monitoring network, or the internet. (column 17, lines 57-65 of Miesel).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-

0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Matthew Kremer
Assistant Examiner
Art Unit 3736
June 4, 2003

ERIC F. WINAKUR
PRIMARY EXAMINER